UK Mini Mitral Privacy Notice

What is the purpose of this study?

Heart surgery to repair one of the valves in the heart (the mitral valve) is commonly performed in the NHS. Patients needing this operation sometimes suffer symptoms of shortness of breath (especially when exercising), tiredness, and swollen ankles, caused by the valve becoming leaky (mitral regurgitation). Some patients suffer very few symptoms. These patients are quite often of working age so time away from their place of work can be difficult for a number of reasons. We need to make sure that the operations offered within the NHS are best for patients. To repair the valve, the operation usually involves cutting the breastbone completely (from the collar bone to the bottom of the breastbone); this is called a sternotomy. An operation has been developed which means that the valve can be repaired using a much smaller cut on the side of the chest; this operation is called a mini- thoracotomy.

This study will compare the two operations in 330 adult patients, to see how well they recover and return to normal activities. The trial will include patients at NHS hospitals across England and Scotland. Patients will be randomised (allocated) to undergo one of the operations. The trial is large enough to show which operation is better for patients and the NHS. We will ask patients who take part questions about their physical activities and quality of life before and after their operation. We will also check other important factors to see how well patients recover, including how well their valve works up to twelve weeks and twelve months after surgery using a heart scan (called an echocardiogram). We will ask patients to wear a device that measures their activity for one week on seven occasions; the device looks like a wrist-watch and can be worn all day and all night. Any complications following a patient's operation will be recorded from their medical records. We will also calculate the costs of care for each operation by looking at medical records to see how often patients are seen in hospital after their operation. Patients who take part will attend hospital a few times in the first year, after this we will continue to check their progress by reviewing their medical notes. We will ask patients to confirm that they are happy that we keep looking at their medical records, even after the trial is finished.

What is the name of the Data Controller?

The Data Controllers for this study are South Tees Hospitals NHS Foundation Trust and Newcastle University. Contact details for the Data Protection Officers can be found below:

South Tees Hospitals NHS Foundation Trust: stees.dpo@nhs.net

Newcastle University: Privacy Notice | Newcastle University | Newcastle University

Newcastle Clinical Trials Unit: Privacy Notice | Newcastle Clinical Trials Unit | Newcastle University

What is the lawful basis for processing your data?

The lawful basis for carrying out this study under GDPR is Task in the Public Interest, (Article 6,1e) as research cited as part of the University's duties. As we are collecting special categories of personal data the second lawful basis is Scientific Research (Article 9, 2j). We have asked participants for consent to take part in the study.

How long will my data be kept?

Your data has to be kept from the end date of the study for a period of 15 years. This includes electronic and paper copies of the information. When data is archived, the data will be completely anonymised.

What if I change my mind and want to withdraw from the study?

You are free to withdraw from the trial at any stage and your future care will not be affected. We ask you to sign a consent form; however you can still withdraw at any stage. The consent form covers who will be notified about your participation and what would happen if you became unwell (lose your ability to make decisions about your health care) after the operation. If you became unwell after the operation, we ask for permission to continue to collect information so that we can identify all complications.

Who will you share data with?

Personal Identifiable Data will be shared with NHS Digital which allows them to flag your records as being part of the UK Mini Mitral clinical trial. De-identified data will only be shared with approved collaborators, whose research aims match or further the goals of this study. De-identified data is data which has had identifiable information removed. Study data will be kept separate from personal information (such as name or date of birth). No individual will be identified or identifiable in any publication arising from the research.

Will my data be looked after safely?

Your personal data are stored in a secure location within NHS Trusts and Newcastle University, with restricted access only given to the study team. Your name, NHS number and Date of Birth may be used in order to access NHS Digital data. All electronic data is stored on a secure network drive with access given only to the study member researchers. When data is shared, information is restricted to the information needed to carry out the task.

Who do I complain to?

You have a right under law to raise a complaint with the Information Commissioners Office (ICO). The ICO is the organisation responsible for enforcing the Data Protection Law within the UK. You can do this using the link below: Information Commissioners Office

Contact details of Newcastle University Study team:

Newcastle Clinical Trials Unit

Newcastle University

1-4 Claremont Terrace

Newcastle upon Tyne

NE2 4AE

Telephone: 0191 208 2522